UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,943	01/29/2004	Yasuyuki Numajiri	00862.023438.	1830

5514 7590 02/27/2008

FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER	
SHAW, AMANDA MARIE	
ART UNIT	PAPER NUMBER
1634	
MAIL DATE	DELIVERY MODE
02/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/765,943	NUMAJIRI, YASUYUKI	
	Examiner	Art Unit	
	AMANDA SHAW	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-9,15,17-19 and 25-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-9,15,17-19 and 25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the amendment filed January 3, 2008. This action is made FINAL.

Claims 6-9, 15, 17-19 and 25-27 are currently pending and will be addressed herein. Claims 6-9, 15, and 26 have been amended. Claim 27 is newly presented. Therefore Claims 6-9, 15, 17-19 and 25-27 will be addressed herein.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-7, 15, 17, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Hogan (US 2002/0110823 Pub 8/2002 Filed 10/2001).

Regarding Claim 6 Hogan teaches a method wherein the same specimen is used to identify a subject and to generate test information for the subject at the same time using a DNA microarray. Specifically Hogan teaches a method of wherein a sample from a perioperative subject is used to generate a genomic profile for that subject. Hogan teaches that in some embodiments the genomic profile includes a set of markers that provide information that can be used to determine the course of treatment (Para 0126). Hogan further teaches that in some embodiments the genomic profile includes a

set of unique genomic identifiers (e.g., a series of polymorphic non coding SNPs), can be used to determine the identity of the subject (Para 0134). Additionally Hogan teaches that in preferred embodiments the genomic profiles are generated using a DNA microarray (Para 0167-0176). Thus Hogan teach a method wherein a sample specimen is used to identify a subject and to generate information on the course of treatment for the subject wherein the specimen is analyzed using a DNA microarray comprising a set of probes which are used to distinguish a subject and a set of probes which are used to test a specimen from the subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of the subject and obtain test information for the subject (Para 0167-0176). Hogan also teaches that once sequence information is generated the information is stored in a database as digital information (Para 0186). Therefore it would be possible to determine if a patient is new by comparing the genomic profile of the patient to the other genomic profiles stored in the database.

Regarding Claim 7 Hogan teaches a method wherein perioperative genomic profiles are generated using computer based data analysis of a genetic information sample (e.g., stored nucleic acid sequence information). A sample is collected from a subject at any time (e.g., at birth), sequence information is generated (e.g., through DNA sequencing), and the information is stored (e.g., as digital information on a portable chip). During the perioperative period the subject's sequence information is scanned by a computer program for the pre selected markers and a report (e.g., a perioperative genomic profile) is generated (Para 0186). Thus Hogan teaches a

method further comprising reading out from a storage unit the identification codes and a past test result.

Regarding Claim 15 Hogan teaches a method of providing a sample from a perioperative subject and generating a genomic profile. Hogan teaches that in some embodiments the genomic profile includes a set of markers that provide information that can be used to determine the course of treatment (Para 0126). Hogan further teaches that in some embodiments the genomic profile includes a set of unique genomic identifiers (e.g., a series of polymorphic non coding SNPs), thus providing a secure, accurate internal reference for archiving and tracking genetic data specific to the particular subject (Para 0134). Hogan also teaches that once sequence information is generated the information is stored is a database as digital information (Para 0186). Additionally Hogan teaches that in preferred embodiments the genomic profiles are generated using a DNA microarray (Para 0167-0176). Hogan further teaches that each subject may have an information card containing his or her genetic information (Para 0189). Therefore it would be possible to compare the subjects identification number acquired from reading the first DNA probe set to the identification number on the subjects information card in order to verify the identity of the subject. Thus Hogan teach a method comprising: reading a hybridization pattern on a DNA microarray comprising a set of probes which are used to distinguish a subject and a set of probes which are used to test the specimen from the subject, analyzing the hybridization state of the probes to identify the subject, analyzing the hybridization state of the probes to acquire test information for the subject, acquiring the subjects information card, and comparing

the subjects identification number acquired from reading the first DNA probe set to the identification number on the subjects information card.

Regarding Claims 17 and 19 Hogan teaches a method wherein perioperative genomic profiles are generated using computer based data analysis of a genetic information sample (e.g., stored nucleic acid sequence information). A sample is collected from a subject at any time (e.g., at birth), sequence information is generated (e.g., through DNA sequencing), and the information is stored (e.g., as digital information on a portable chip). Thus Hogan teaches a method further comprising recording on the medical information card the test information generated and the personal identification information generated.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 8-9 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (US 2002/0110823 Pub 8/2002 Filed 10/2001) in view of Noblett et al (US Patent 6362004 Issued 2002).

Hogan teaches a method wherein the same specimen is used to identify a subject and to generate test information for the subject at the same time using a DNA microarray. Specifically Hogan teaches a method of wherein a sample from a perioperative subject is used to generate a genomic profile for that subject. Hogan teaches that in some embodiments the genomic profile includes a set of markers that provide information that can be used to determine the course of treatment (Para 0126). Hogan further teaches that in some embodiments the genomic profile includes a set of unique genomic identifiers (e.g., a series of polymorphic non coding SNPs), can be used to determine the identity of the subject (Para 0134). Additionally Hogan teaches that in preferred embodiments the genomic profiles are generated using a DNA microarray (Para 0167-0176). Thus Hogan teach a method wherein a sample specimen is used to identify a subject and to generate information on the course of treatment for the subject wherein the specimen is analyzed using a DNA microarray comprising a set of probes which are used to distinguish a subject and a set of probes which are used to test a specimen from the subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of the subject and obtain test information for the subject (Para 0167-0176). Hogan also teaches that once sequence information is generated the information is stored in a database as digital information (Para 0186). Therefore it would be possible to determine if a patient is new by comparing the genomic profile of the patient to the other genomic profiles stored in the database.

Hogan does not teach that the DNA microarray has a first indicator which indicates the first DNA probe group and a second indicator which indicates the second

DNA probe group. Hogan further does not teach a method wherein the first DNA probe group and the second DNA probe group are arranged on different areas of the same support.

However Noblett teaches the use of fiducial marks on microarrays to precisely determine the location of each probe on the array. Noblett et al teach that microarrays may contain multiple fiducials which can be used for positioning. Additionally Noblett teaches that fiducials can be used to differentiate between arrays when there are multiple arrays on a microarray (Column 7, lines 55-60).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Honda so as to have used a DNA microarray comprising a set of fiducials as suggested by Noblett for the benefit of being able to use the fiducial marks to precisely place the location of all hybridized spots on the array and to differentiate between arrays when there are multiple arrays on a single microarray support (Column 7, lines 55-60).

5. Claims 18 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (US 2002/0110823 Pub 8/2002 Filed 10/2001) in view of Beecham (US Patent 5876926 Issued 1999).

Hogan teaches a method wherein the same specimen is used to identify a subject and to generate test information for the subject at the same time using a DNA microarray. Specifically Hogan teaches a method of wherein a sample from a

perioperative subject is used to generate a genomic profile for that subject. Hogan teaches that in some embodiments the genomic profile includes a set of markers that provide information that can be used to determine the course of treatment (Para 0126). Hogan further teaches that in some embodiments the genomic profile includes a set of unique genomic identifiers (e.g., a series of polymorphic non coding SNPs), can be used to determine the identity of the subject (Para 0134). Additionally Hogan teaches that in preferred embodiments the genomic profiles are generated using a DNA microarray (Para 0167-0176). Thus Hogan teach a method wherein a sample specimen is used to identify a subject and to generate information on the course of treatment for the subject wherein the specimen is analyzed using a DNA microarray comprising a set of probes which are used to distinguish a subject and a set of probes which are used to test a specimen from the subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of the subject and obtain test information for the subject (Para 0167-0176). Hogan also teaches that once sequence information is generated the information is stored in a database as digital information (Para 0186). Therefore it would be possible to determine if a patient is new by comparing the genomic profile of the patient to the other genomic profiles stored in the database.

Hogan does not teach a method further comprising outputting a warning when it is determined that the subjected identified based on the first DNA probe group does not match the subjects profile recorded on the medical information card. Hogan does not teach a method further comprising inhibiting the reading of the test results if the subjects do not match.

However Beecham teaches a method wherein the biometric data submitted by the user does not match stored biometric data the data retrieval process is either terminated or the user is asked to enter new or revised biometric data (Column 18. lines 8-20). This is being interpreted as a warning. Beecham further teach that when the biometric data submitted by the user does not match stored biometric data no stored medical information can be released until the biometric data being entered by the user matches the biometric data stored in the database (column 18, lines 8-20).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hogan by adding a step of outputting a warning when it is determined that the subject being identified does not match the subjects profile on the medical information and inhibiting the reading of the test results as suggested by Beecham (Column 18, lines 8-20). Using the method suggested by Beecham would have been obvious it would have been obvious because it prevents someone from obtaining someone else's private medical information.

6. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (US 2002/0110823 Pub 8/2002 Filed 10/2001) in view of Anderson (PG Pub 20010012537).

Hogan teaches a method wherein the same specimen is used to identify a subject and to generate test information for the subject at the same time using a DNA microarray. Specifically Hogan teaches a method of wherein a sample from a perioperative subject is used to generate a genomic profile for that subject. Hogan

teaches that in some embodiments the genomic profile includes a set of markers that provide information that can be used to determine the course of treatment (Para 0126). Hogan further teaches that in some embodiments the genomic profile includes a set of unique genomic identifiers (e.g., a series of polymorphic non coding SNPs), can be used to determine the identity of the subject (Para 0134). Additionally Hogan teaches that in preferred embodiments the genomic profiles are generated using a DNA microarray (Para 0167-0176). Thus Hogan teach a method wherein a sample specimen is used to identify a subject and to generate information on the course of treatment for the subject wherein the specimen is analyzed using a DNA microarray comprising a set of probes which are used to distinguish a subject and a set of probes which are used to test a specimen from the subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of the subject and obtain test information for the subject (Para 0167-0176). Hogan also teaches that once sequence information is generated the information is stored in a database as digital information (Para 0186). Therefore it would be possible to determine if a patient is new by comparing the genomic profile of the patient to the other genomic profiles stored in the database.

Hogan does not teach a method further comprising a step of identifying the microarray.

However Anderson et al teach that it is important to have identifiers on the microarrays. Anderson et al teach that the identifiers may be part of the array itself or the array may have a machine-readable indicia such as a barcode to provide identification and orientation (Para 0125).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hogan et al so as to have used a microarray which has a barcode as suggested by Anderson for the benefit of being able to scan the barcode to determine the identity of the microarray (Para 0125).

Response To Arguments

7. In the response filed January 3, 2008, the Applicants traversed the rejection made over Hogan. The first argument is that Hogan does not teach distinguishing the subject by using a unique genomic identifier. The Applicants point to the specification (para 0134) for support and assert that the unique genomic identifier provides an internal reference indicative, for example, of a place of the gene to be observed. The Applicants believe that the genomic identifier in Hogan does not distinguish a subject, it distinguishes data. The argument has been fully considered but is not found persuasive. Hogan teaches that "In some embodiments, the perioperative genomic profile includes a unique genomic identifier (e.g., a series of polymorphic non coding SNPs), thus providing a secure and accurate internal reference for archiving and tracking genetic data specific to the particular subject". In other words Hogan is saying that the genomic profile includes SNPs that a specific to the particular subject, therefore the SNP profile can be used to determine the identity of the subject.

The Applicants further argue that Hogan fails to disclose or suggest associating the unique genomic identifier with a probe on the DNA chip and that Hogan fails to disclose or suggest a probe group for identifying a subject. This argument has been

fully considered but is not found persuasive. Hogan teaches (para 0134) that the genomic profile may include a unique genomic identifier and further teaches (para 0168) that the genomic profiles are generated using a DNA chip hybridization assay. Thus Hogan teaches the association of the unique identifier with a probe or set of probes on a DNA chip. Further Hogan teaches (para 0134) that the unique identifier can be a series of polymorphic non coding SNPs, therefore multiple probes would be required to detect the series of SNPs. Thus Hogan teaches a probe group for identifying a subject.

Finally the Applicants argue that Hogan does not disclose or suggest utilizing an genetic information card for distinguishing the subject. However the specification teaches (para 0189) an information card containing the genetic information can be scanned by a computer and the data transmitted to a genomic profiling center where a genomic profile is produced. In it is inherent that if the information card contained information on SNPs specific to a particular subject, then the information card could also be used to identify the subject. Therefore the rejection over Hogan is maintained.

The response also traversed the rejections made over Hogan in view of Noblett, Hogan in view of Beecham and Hogan in view of Anderson. The Applicants main argument is that these references can not cure the deficiencies of Hogan. The examiner disagrees that the Hogan reference is deficient for the reasons presented above. Therefore the Hogan in view of Noblett, Hogan in view of Beecham and Hogan in view of Anderson rejections are maintained.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634

/Juliet C Switzer/

Primary Examiner, Art Unit 1634